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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,766	12/29/2006	Hideki Hasegawa	43512-103808	5560

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EXAMINER
BOESEN, AGNIESZKA

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
05/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/567,766	HASEGAWA ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/22/08; 7/28/08; 5/8/08; 12/29/06.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received February 18, 2009.

Election/Restrictions

Applicant's election without traverse of group II, claims 11-14 is acknowledged. Claims 1-10 and 15-18 are withdrawn because the claims are drawn to the non-elected invention.

Claims 11-14 are under examination in this Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/22/2008, 7/28/2008, 5/8/2008 and 12/29/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing immune responses against an infectious disease or for preventing influenza infection, does not reasonably provide enablement for a method of preventing an infectious disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention.

The claims are drawn to a method of preventing an infectious disease comprising administering double-stranded RNA comprising Poly (I: C) and a subunit antigen. The present claims are rejected because the present specification does not provide an adequate enablement for the claimed method of preventing any infectious disease, as discussed below.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un)predictability of the art, and the breadth of the claims.

The present claims are drawn a method of preventing an infectious disease comprising administering double-stranded RNA comprising Poly (I: C) and a subunit antigen or inactivated antigen of a pathogen. The present claims encompass a large genus of infectious diseases; including diseases caused by pathogenic organisms such as for example HIV, HBV or HSV. The

present specification contemplates making vaccine compositions comprising double-stranded RNA comprising Poly (I: C), against pathogens such as SARS, HIV, HSV, *Vibrio cholerae* and other (specification page 40). The recitation of "preventing an infectious diseases" indicates complete absence of infection and disease after exposure to pathogenic organisms in subjects treated with double-stranded RNA comprising Poly (I: C) and a subunit antigen or inactivated antigen of a pathogen. The recitation of "antigen" and "pathogen" reads broadly on antigens from any known pathogenic organisms. In support for the present claims the specification discloses working Examples showing generation of protective and prophylactic immune responses in mice by administering inactivated influenza virus and double-stranded RNA comprising Poly (I: C) Examples 1-7). Example 8 shows enhancement of immune responses by nasal administration of pertussis vaccine together with Poly (I: C). Example 11 shows prophylactic effect of varicella vaccine administered along with Poly (I: C) in humans.

While protective vaccine against influenza currently exists (as taught by Arnoux et al. Vaccine, 2007, Vol. 25, p. 7720-7731) as well as the art teaches influenza vaccines and other immunogenic compositions comprising Poly (I: C) (see US Patent 7,132,271, 7,410,975 B2, and 7,354,909 B2) the art does not teach protective vaccines against pathogenic organisms such as HIV, HSV, SARS and many other encompassed by the claims. Letvin, 2006, Nature Immunology, Vol. 6, p. 930-939 teaches obstacles to developing a successful therapy of HIV are well documented in the literature. These obstacles include 1) the extensive genomic diversity and mutation rate associated with the HIV retrovirus, particularly with the respect to the gene encoding the envelope protein. 2) The fact that the mode of viral transmission includes both virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert manner,

as well as via free virus transmission. 3) The establishment of a latent viral infection. 4) The ability of the virus to evade the immune responses in the central nervous system due to the blood-brain barrier. 5) The complexity and variation of the pathology of HIV infection in different individuals. 6) The inability of a natural infection to one strain of HIV to protect an individual from being infected with another strain of HIV (Machuca et al. Intervirology 1999, Vol. 42 p. 37-42, see discussion). These obstacles establish that the contemporary knowledge in the art would not allow one of skill in the art to practice the claimed method that read on preventing HIV infection without undue experimentation. The present specification does not provide sufficient guidance for the skilled artisan to conclude that the claimed method can result in prevention of any infectious diseases. The specification does not provide adequate support for the large genus if infectious diseases.

Applicants have not provided convincing evidence that their claimed method is indeed effective in preventing infectious diseases and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure to support the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Journal of Clinical Investigation, 2002, Vol. 110, p. 1175-1184).

Wang discloses methods of inducing immune responses against infectious diseases comprising mucosally (intranasally) administering double-stranded RNA comprising Poly (I:C) and a subunit antigen (see the entire document, particularly Methods).

Thus by this disclosure Wang anticipates the present claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Examiner, Art Unit 1648